

Scientific Advisory Committee on Nutrition

Paper for information: Fructo-oligosaccharides (FOS) and Galacto-oligosaccharides (GOS) in Infant Formulae

Agenda Item 7

Please see attached paper for information.

Annexes available from the secretariat

1. European Commission Health and Consumer Protection Directorate-General, Scientific Committee on Food Statement on the use of resistant short chain carbohydrates (oligofructose and oligogalactose) in infant formulae and in follow-on formulae, 26 September 2001
2. European Commission Health and Consumer Protection Directorate-General, Scientific Committee on Food Additional Statement on the use of resistant short chain carbohydrates (oligofructosyl-saccharose and oligogalactosyl-lactose) in infant formulae and in follow-on formulae, 14 December 2001

Members may wish to refer to the following papers available on request from the secretariat.

1. Ad hoc Expert Group on Child Nutrition, Minutes of the meeting held on 1 December 2000, Item 5
2. AFSSA (2001), Avis de l'Agence française de sécurité sanitaire des aliments relatif à l'évaluation de deux préparations pour nourisseries. Opinion Expressed on 31 July 2001. Available on (Opinion/advice of French Agency of medical security of food relating to the evaluation of two infant preparations.)
3. Bouhnik Y, Vahedi KAL, Attar A, Salfati J, Pochart P, Marteau P, Flourie B, Bornet F, Rambaud JC (1999). Short-chain fructo-oligosaccharide administration dose-dependently increases faecal bifidobacteria in healthy humans. *J Nutr* 129: 113-116.
4. NUMICO comment on questions raised by the statement of the SCF on the use of resistant short chain carbohydrates (oligofructose and oligogalactose) in infant formulae and in follow-on formulae, expressed on September 26, 2001

Scientific Advisory Committee on Nutrition

Fructo-oligosaccharides (FOS) and Galacto-oligosaccharides (GOS) in Infant Formulae

ISSUE

The UK and other European Member States have raised concerns over the safety of FOS and GOS in infant formulae.

BACKGROUND

There are two products available in the UK containing FOS and GOS, Omneo Comfort Stage 1 and 2 marketed by Nutricia. The products are intended to stimulate the growth and activity of beneficial intestinal bacteria and alleviate symptoms of colic. Concerns have been raised concerning Omneo Comfort 1. Members may wish to refer to the paper SACN 01/08 concerning Omneo Comfort 1 and the Welfare Foods Scheme.

Scientific Committee on Food

At the request of the European Commission, prompted by concerns in a number of Member States, the Scientific Committee on Foods (SCF) considered the safety of infant formulae containing FOS and GOS. The SCF's initial conclusion, when they met in September 2001, was that:

'There are insufficient data to establish safe use of FOS and GOS as ingredients of infant formulae, which serve as the sole diet of infants during the first months of life. Appropriate studies should evaluate the potential adverse effects, particularly with respect to water balance and nutrient bioavailability.'

Concerns of the SCF include increased stool frequency and reduced stool consistency resulting in possible dehydration in young infants. The SCF noted the particular risk

to infants undergoing water balance stress, for example during times of fever and infectious diarrhoea. Other safety aspects of concern were a more rapid intestinal transport of loose stools with the potential to interfere with the bioavailability of substrates¹. The SCF considered the risk of adverse effects amongst older infants to be very low and raised no concern about the use of FOS and GOS in follow-on formulae.

One manufacturer contested the SCF's conclusion in relation to Omneo Stage 1 and submitted additional supporting information. In December 2001 the Committee issued the following statement;

“The additional information made available, in particular with respect to growth and markers of water balance, does not provide any indication of adverse effects from the use of a formulae with up to 0.8 g/dl of a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Based on this data the Committee has no major concerns about this combination of oligofructosyl-saccharose and oligogalactosyl-lactose in infant formulae and follow-on formulae in total concentrations up to 0.8 g/dl in the product ready for consumption”. (Omneo Comfort Stage 1 contains GOS at an amount lower than this).

The Committee recommended that further information be collected on the suitability of short chain carbohydrates in infant formulae and follow-on formulae with particular attention given to the effects on growth and body composition, nutrient bioavailability, water balance, urine output and urine osmolarity in infants and neonates.

The Committee noted that short chain carbohydrates are to be reviewed further as part of the ongoing evaluation of the compositional requirements of infant formulae and follow-on formulae.

¹ Substance on which enzymes act

ACTION

No further action proposed on this issue at this stage.

SACN Secretariat

February 2002